IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **HON. JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF MICHAEL KARRAM, MD

Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude expert testimony of Michael Karram, MD, FAGOC, FPMRS (Doc 2849).

INTRODUCTION

Dr. Karram is a urogynecologist nationally and internationally known in the field of gynecologic surgery and advanced pelvic surgery, with a subspecialty in the field of Female Pelvic Medicine and Reproductive surgery. Karram Expert Report Doc. 2851-3 at 1-2 (Ex. C to Plaintiffs' Motion). He is board-certified in obstetrics and gynecology since 1986 and female pelvic medicine and reconstructive surgery since 2014. *Id.* Dr. Karram has been in private practice since 1984, currently serving as the Director of Urogyecology at Seven Hills Women's Health Centers in Cincinnati, Ohio (since 1998), Director of Fellowship Minimally Invasive Gynecologic Surgery at Christ Hospital in Cincinnati (sic) (since 2013), and the Medical Director of Pelvic Floor Center at Mercy West Hospital in Cincinnati (since 2015). *Id.* He is a member of the American Urogynecologic Society (AUGS), International Urogynecologic Association (IUGA), and the American Association of Gynecologic Laparoscopists (AAGL). *Id.*

at 3. He has worked as a consultant, proctor, preceptor, and trainer for pharmaceutical companies, including for Ethicon for TVT and TVT-O. *Id.* at 2, 20-21. Dr. Karram is an expert in treating both stress urinary incontinence and pelvic organ prolapse, with extensive experience using both native tissue and augmented repairs. *Id.* at 1. He began using TVT in 1998 and has performed over 2,000 synthetic sling procedures. *Id.* at 4.

In these cases, Dr. Karram intends to offer opinions generally addressing the utility and safety of various mesh devices, including TVT and TVT-O. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other materials reflected in his reliance list. *Id.*; Karram Expert Report Reliance List (attached as Ex. A). He is qualified to opine on these topics and, as detailed below, his opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Karram's opinions, and, as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions as articulated by the court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Karram's opinions regarding Ethicon's warnings for the TVT and TVT-O devices are (1) relevant to the appropriate legal standard, i.e., the adverse event risks commonly known to pelvic floor surgeons, and to the risks said to be unique to mesh, and (2) well-supported by reliable methodology and are, therefore, admissible.

Despite Plaintiff's argument to the contrary, Dr. Karram is qualified to opine about Defendants' IFUs and warnings, and his opinions are well supported by reliable methodology. "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling

and warnings." *Winebarger v. Boston Sci. Corp*., No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)). In its Wave 1 decisions on expert testimony, the Court distinguished between the types of opinions urogynecologists may offer on Ethicon's IFUs. These physicians, like Dr. Karram, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See In re Ethicon, Inc.*, 2016 WL 452054, at *3. Conversely, they "must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *Id.* Dr. Karram does not intend to opine that Ethicon's IFUs should or should not have included certain risks as a matter of law and does not attempt to articulate the legal standards. In fact, he admitted that he is not a regulatory expert. Karram Expert Report Doc. 2851-3 at 22 (Ex. C to Plaintiffs' Motion). The important question here is whether Dr. Karram's testimony was consistent with the law to be applied to the case, and not whether he himself could articulate the governing legal standard.

In support of their failure-to-warn claims, Plaintiffs offer experts who have identified a host of alleged risks and complications to mesh surgery that they contend do not appear on the relevant IFUs. In response, Ethicon is offering physicians, like Dr. Karram, to testify as to which of those risks and complications identified by Plaintiffs' experts are known by surgeons to be common with all pelvic surgeries and, conversely, whether those risks and complications that are truly unique to mesh surgery are covered by the IFU.

This testimony is critical to Ethicon's "common knowledge" defense under the applicable legal standard establishing the risks and complications that needed to be included in the IFUs. Moreover, this testimony is consistent with this Court's ruling that urognyecologists may testify

about the risks of implanting mesh and whether they are discussed in the IFU. Dr. Karram is well-qualified to offer this testimony, including identifying those risks and complications known by surgeons to be common with all pelvic surgeries, based on both his extensive experience and research. Also, this is a proper subject for expert testimony as numerous courts have held that experts may testify as to whether certain risks associated with a device are commonly known by foreseeable users.

The legal standard. Dr. Karram's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of the person whose use is at issue in the particular case. *Johnson v. American Standard, Inc*., 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the

medical community"). In fact, the FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.109(c). *See also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc*., 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd*., 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence and pelvic organ prolapse. The TVT IFU says "[u]sers should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system" and that it "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)." (ETH.MESH.00875456 (excerpts attached as Ex. B)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH.02340830 (excerpts attached as Ex. C)). So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery at the time of implantation. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the

very least, unique to the use of the mesh in that application – surgery to treat stress urinary incontinence.

What counts here is the legal standard and under that standard a manufacturer does not have a duty to warn of things likely users already know. What they know is precisely the evidence that Dr. Karram has provided.

This evidence is also properly provided through expert testimony. Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts "that it is known within the correctional medical community that some inmates seek the prescriptions Klonopin and Remeron not for their proper medical indications, but rather for their common side effects, which make patients less aware of their surroundings"). In a products liability action, experts may also testify as to those risks that are commonly known by plaintiff-users asserting failure-to-warn claims. *See Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (holding, in a tobacco liability case, that such evidence needed to be offered through expert testimony as "[t]he 'common knowledge' defense is assessed objectively, and, despite the nomenclature, it is a technical question involving methods, financing, and sources of research beyond the competence of lay determination, at least when pertaining to history forty or fifty years removed from the time of trial"). The same holds true here. The proper vehicle for offering evidence as to which of the risks and complications identified by Plaintiffs were already commonly known by surgeons is through physician-experts, like Dr. Karram.

Dr. Karram's qualifications. Dr. Karram's opinion rests not only on his own education, training, and extensive experience treating SUI with both native tissue and mesh procedures,

including TVT and TVT-O, as discussed above, but on his review of the medical literature and years of experience in teaching other pelvic floor surgeons on treating SUI with TVT and TVT-O. Karram Expert Report Doc. 2851-3 at 22-23 (Ex. 2 to Plaintiffs' Motion). He also considered statements by medical professional associations and regulatory bodies. *Id.* In sum, Dr. Karram does not rely on his personal experience or "personal beliefs" alone, as Plaintiffs argue. This makes him well-qualified to testify as to what is "commonly known" to those surgeons, an essential fact necessary when evaluating the "adequacy" of the IFU.

In his opinion, surgeons already know the surgical risks and complications of traditional non-mesh surgery. Those complications include pain, infection, urinary problems, recurrent incontinence, dyspareunia, bleeding, organ perforation, neuro-muscular problems and vaginal scarring. *Id.* at 22-23 & n.1. It is Dr . Karram's opinion that the IFU identifies and describe those risks specific or unique to TVT and TVT-O including mesh erosion, and that the other "surgical risks and complications (as opposed to warnings about alleged design deficiencies) that plaintiffs' experts opine should be included in the TVT and TVT-O IFUs are risks that are commonly known to pelvic floor surgeons." *Id.* at 22. This is testimony that directly addresses the appropriate legal standard, which cannot be applied without evidence of what is "commonly known" to the class of foreseeable users about the risks of the surgery. Because it is consistent with the applicable legal test, it "fits" this case whether or not Dr. Karram himself can testify to the details of that law.

II. Dr. Karram's opinions regarding knowledge common to pelvic surgeons are not state of mind testimony, are relevant to the applicable legal standard, are well-supported, and, therefore, are admissible.

In its Wave 1 opinions on expert testimony, including its opinions on the testimony of Dr. Karram, this Court has consistently held that "state-of-mind" testimony about the specific

knowledge of other people, including "all surgeons" or "all patients," is inadmissible because it would "usurp the jury's fact-finding duties." *See In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation*, MDL No. 2327, 2016 WL 4944522, at *3 (S.D. W. Va. Sept. 2, 2016). Plaintiffs now attempt, under the umbrella of "state-of-mind" testimony, to exclude Dr. Karram's relevant and admissible testimony regarding knowledge common to the class of foreseeable users of TVT and TVT-O, which, as discussed above, is consistent with the applicable legal test. Such attempts must fail.

Dr. Karram is not providing opinions on what "all surgeons" know or should know so as to usurp the jury's fact-finding duties with regard to the particular knowledge of the specific healthcare providers, such as the implanting physicians who provided care to the plaintiffs in the cases at hand. Rather, Dr. Karram is opining on knowledge common to pelvic surgeons, the specific group of intended users of TVT and TVT-O and intended recipients of the IFUs, which, as discussed above is relevant to the applicable duty to warn in a failure to warn case and is admissible expert testimony. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users); *see also Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003).

Furthermore, Dr. Karram's opinions regarding knowledge common to all pelvic surgeons are well-supported. Contrary to Plaintiffs' misuse of Dr. Karram's prior testimony regarding the Prolift device, Dr. Karram has not "acknowledged that he has no evidence or scientific basis" for these opinions. While Dr. Karram did acknowledge that his Prolift opinions were not based on any specific study generally reviewing "general knowledge of surgeons," Karram 6/28/16 Dep.

Doc. 2851-2 at112:8-11 (Ex. B to Plaintiffs' Motion), as discussed above, his opinions rest on a broad range of bases, including his education, training, and extensive experience treating SUI with both native tissue and mesh procedures, including TVT and TVT-O, and his review of the medical literature and years of experience in teaching other pelvic floor surgeons in treating SUI with TVT and TVT-O. Karram Expert Report Doc. 2851-3 at 22-23 (Ex. C to Plaintiffs' Motion). These training opportunities not only serve as a basis for Dr. Karram's knowledge of the information attending pelvic surgeons receive during the training, but provide Dr. Karram with a unique "forum in which [he has] received a tremendous amount of feedback" from other pelvic surgeons, providing insight into the knowledge common to this group. *Id.* at 23. Dr. Karram's opinions are also informed by his attendance at medical conferences and professional society meetings and statements by medical professional associations and regulatory bodies. *Id.* This makes him well-qualified to testify as to what is "commonly known" to those surgeons, and because that is an essential fact necessary when evaluating the "adequacy" of the IFU, Dr. Karram's opinions regarding the common knowledge of pelvic surgeons is relevant and admissible.

III. Dr. Karram is qualified to offer opinions regarding mesh's reaction to and effect on the human body, and such opinions are based on reliable methodology.

Finally, Dr. Karram is qualified to opine about the reaction of the body to mesh and mesh's effects on the body, and his opinions are well supported by reliable methodology. In his report, Dr. Karram offers opinions regarding the general biocompatibility of Prolene mesh with the body, the potential (or lack thereof) for malignant effects on the body from Prolene mesh, and other alleged effects and reactions of the body to mesh, including inflammation, infection, rejection, and healing issues. Karram Expert Report Doc. 2851-3 at 24-28 (Ex. C to Plaintiffs' Motion). In other words, Dr. Karram's opinions about the safety and efficacy of the TVT and

TVT-O necessarily incorporate his clinical observations and knowledge gleaned from extensive review of medical literature about the biocompatibility of the materials used in the TVT and TVT-O products. Contrary to Plaintiffs' arguments, however, these opinions are not opinions regarding the "biomechanical design" of the mesh. They do not address the details of the chemical composition or detailed properties of the Prolene mesh. To that end, Dr. Karram's admitted lack of expertise in biomaterials, pathology, or biomechanical engineering, as well as any purported limitations on his detailed understanding of the specific construction of mesh, are immaterial to the admissibility of his actual opinions.

As previously noted by this Court, clinicians experienced with mesh can provide sufficient qualification to offer opinions about "how the product reacts within the body." *Winebarger*, 2015 WL 1887222, at *26; *see also Tyree*, 54 F. Supp. 3d at 585 (finding urogynecologist who has performed almost 3,000 sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infection); *Huskey*, 29 F. Supp. 3d at 734 (finding Dr. Johnson qualified to opine as to mesh degradation); *Carlson v. Boston Sci. Corp.*, No. 2:13-CV-5475, 2015 WL 1931311, at *9–19 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *In re: Ethicon, Inc.*, 2016 WL 4536885, at *3 (holding that Dr. Margolis, a urogynecologist, was qualified to testify regarding biomaterial properties including mesh reaction to and effect on the human body). Like these physicians, Dr. Karram, who has performed over 2,000 sling procedures in the last 18 years, is an expert in his field, and has trained numerous other physicians on the implantation of slings, *see* Karram Expert Report Doc. 2851-3 at 1-2, 20-21 (Ex. C to Plaintiffs' Motion), is well qualified to make such opinions.

Furthermore, despite Plaintiffs' general charge that Dr. Karram followed no reliable methodology in forming these opinions, Plaintiffs provide no clarification for this statement and seem to rest the methodology argument on Dr. Karram's general qualifications. Not only is Dr. Karram well-qualified to offer the opinions he does, his opinions are explicitly based not only on his "own clinical experience treating thousands of women with polypropylene products" but on the extensive medical literature reviewed and read during his practice. *Id.* at 25. For example, in his report, Dr. Karram cites to the 2015 Cochrane review, the 2014 AUGS/SUFU joint position statement, literature published by Peter Petros, studies performed by both the Cleveland Clinic and the Mayo Clinic, and others. *See id.* at 24-28. He also identifies a lack of level I scientific data contradicting the generally reported safety and efficacy of the mesh. *Id.* Plaintiffs fail to provide any explanation for their contention that these methods of forming opinions are "unreliable."

In sum, Dr. Karram may not be qualified to offer advanced pathology opinions, but he does not purport to offer such opinions. Instead, Dr. Karram's opinions are drawn from his own extensive clinical experience actually treating thousands of women with mesh slings like the TVT and TVT-O, as well as his thorough review of high-level scientific literature. The Court should deny Plaintiffs' motion on this ground.

CONCLUSION

For the forgoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude the testimony of Dr. Karram regarding the safety and efficacy of the TVT and TVT-O products.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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